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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,476	03/29/2004	Douglas C. Harrington	17.003001 CON 2	3267
38732 7590 05/29/2009 CYTYC CORPORATION Darry Pattinson, Sr. IP Paralegal 250 CAMPUS DRIVE MARLBOROUGH, MA 01752				
EXAMINER ROANE, AARON F				
ART UNIT		PAPER NUMBER		
3769				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,476

Applicant(s)

HARRINGTON ET AL.

Examiner

Aaron Roane

Art Unit

3769

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-22, 27-40 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-22, 27-40 and 45-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/6/2009.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9, 10, 13, 17, 19-22, 27, 28, 31, 35, 37-40, 45, 46 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (U.S. Patent 5,095,917) in view of Tay et al. (U.S. Patent 5,810,810) and further in view of Zeluff (U.S. Patent 4,606,336).

Regarding claims 1-4, 9, 10, 19-22, 27, 28, 37-40, 45 and 46, Vancillie discloses a method of occluding the ovarian pathway of a female body said method comprising the

steps of: applying a heating element in the form of a catheter-mounted high frequency bipolar electrode array (33) to a target segment of the pathway, and operating the heating element to heat the target segment in the pathway; limiting the heating of the target segment by applying power of 0.1 to 5 watts to the heating element for a period of at least about 5 seconds; and installing a plug into the target segment of the pathway, see col. 1-6, particularly col. 2, line 28 through col. 3, line 22 and figures 1-6. It should be further noted that the electrode array (33) is mounted on a catheter ("hollow tube" 30). Although it is well known in the art that high frequency includes radio Frequency (RF), Vancillie fails to explicitly recite that the high frequency bipolar electrode array is explicitly a Radio Frequency (RF) bipolar electrode array. Additionally, Vancillie fails to disclose the claimed invention except for the plug being reticulated foam having a pore size of 40-200 microns or 1-20 microns. Vancillie disclose that the plug is an expandable, absorbable plug. However, Vancillie falls short of explicitly reciting the plug is a sponge or foam. Tay et al. disclose an electrode surgical medical device and teach "the frequency of the alternating electrical energy can be anywhere in the radio frequency range (10 kHz to 300 GHz). For medical reasons, the frequency should be above 25 kHz. For most applications, a high frequency energy range, generally 300 kHz to 1,000 kHz, may be used, with the frequency preferably being in the range of 300 kHz to 600 kHz, more preferably between 450 kHz and 550 kHz, and most preferably 500 kHz. In other applications, frequencies in the short wave range (10 MHz to 100 MHz), or in the microwave range (1 GHz to 300 GHz), will be more useful," see col. 11:57 – col. 12:10. Zeluff discloses an apparatus and method for sterilizing female reproductive organs and

teaches providing a plug made of an expandable porous structure in order to promote ingrowth of fibroblast and create a hermetic seal at the uterotubal junction, see col. 3, line 28 through col. 4, line 23. Zeluff further discloses that the pore size is "on the order of 2 microns or greater," see col. 4, lines 56-64 and figures 1-12. It should be noted that an expandable porous material meets the claimed foam and reticulated foam structure. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie, as taught by Tay et al., to explicit use RF for the high frequency energy delivery in order to provide energy to tissue, as further taught by Zeluff, to make the plug from a porous foam having pore size "on the order of 2 microns or greater" in order to promote ingrowth of fibroblast and create a hermetic seal at the uterotubal junction.

Regarding claims 13, 17, 31, 35, 49 and 53, Vancillie in view of Tay et al. in further view of Zeluff disclose the claimed invention of the foam plug in the form of an ePTFE plug, see Zeluff col. 4, lines 42-63.

Claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (U.S. Patent 5,095,917) in view of Tay et al. (U.S. Patent 5,810,810) and further in view of Zeluff (U.S. Patent 4,606,336) as applied to claims 9, 10, 27, 28, 45 and 46 above, and further in view of Barbacci (U.S. Patent 5,531,741).

Regarding claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52, Vancillie in view of Tay et al. in further view of Zeluff disclose the use of silicone plugs for tubul occlusion, but fail to recite the silicone plug has a durometer of 1-200 Shore A and/or 60 Shore A. Barbacci discloses a uterine and/or fallopian tube stent and teach providing a stent made of silicone rubber having a durometer of 55 to 70 Shore A in order to provide comfort, see col. 7, lines 28-55, col. 8, line 66 through col. 9, line 11 and figures 1-22. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vancillie in view of Tay et al. in further view of Zeluff, as taught by Barbacci, to provide a plug made of silicone having a durometer of 55 to 70 Shore A in order to provide comfort.

Claims 14, 18, 32, 36, 50 and 54 rejected under 35 U.S.C. 103(a) as being unpatentable over Vancillie (U.S. Patent 5,095,917) in view of Tay et al. (U.S. Patent 5,810,810) and further in view of Zeluff (U.S. Patent 4,606,336) as applied to claims 9, 10, 27, 28, 45 and 46 above, and further in view of Brundin (U.S. Patent 4,509,504).

Regarding claims 14, 18, 32, 36, 50 and 54, Vancillie in view of Tay et al. in further view of Zeluff disclose the claimed invention except for the plug made of an acrylic copolymer. Brundin discloses an apparatus and method for occluding body channels including the female reproductive organs and teaches using an expandable plug (2) made of acrylic copolymers in order to provide a biocompatible seal, see col. 2, lines 18-41 and figures 1-6. Therefore at the time of the invention it would have been obvious to one of

ordinary skill in the art to modify the invention of Vancillie in view of Tay et al. in further view of Zeluff, as taught by Brundin, to provide a plug made of an alternate material in the form of an acrylic copolymer in order to make a biocompatible seal.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 9-22, 27-40 and 45-54 have been considered but are moot in view of the new ground(s) of rejection.

As a courtesy to Applicant and in the hopes of expediting prosecution, the examiner would like to comment on some of Applicant's arguments/remarks.

In general regarding Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant may have been able to anticipate the present rejections as they are based on prior art of record and Applicant acknowledged their possible combination on page 10, next to last paragraph, Wherein the references are attacked individually and not as a whole. It should be noted, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re

Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

This action is made non final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
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